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Pharmaceutical Sciences

# COVID-19 Vaccine Basics: The Why, What, Where & When

February 11<sup>th</sup>, 2021

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# Panelists



*Jan Hirsch – Moderator  
Founding Dean*



*Rob Spitale – Panelist  
Founding Associate Dean of Research*



*Alex Chan – Panelist  
Founding Chair*



*Keri Hurley Kim – Panelist  
Health Sciences Assistant Clinical Professor*

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# What will be covered?

- Why are Vaccines Important
- Basics about how vaccines work
- Safety & Efficacy of vaccinations
- Distribution of vaccinations

## Orange County's tier rating

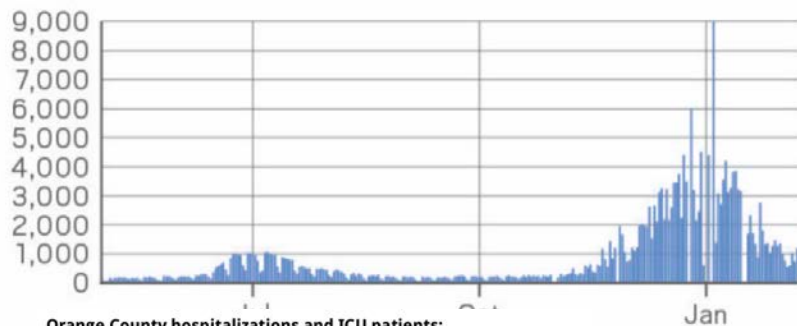
Positive cases per 100K                      39  
Testing positivity rate:                      10.9%  
State threshold:                                >8%

		Rate /100K	Test positivity
	Widespread	>7	>8%
	Substantial	4-7	5-8%
	Moderate	1-3.9	2-4.9%
	Minimal	<1	<2%

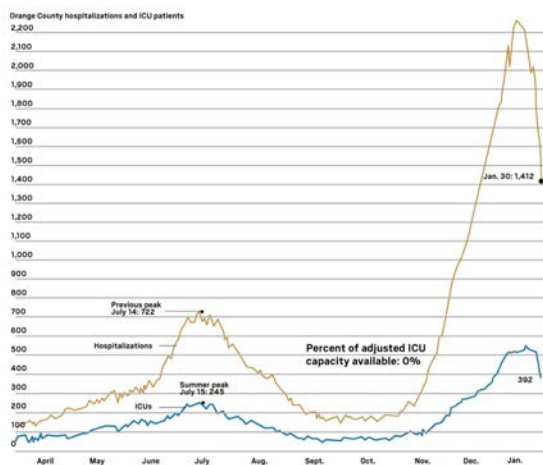
California assigns each county to a tier, based on the prevalence of the coronavirus in the community, that determines how tightly businesses will be restricted. Details at: [covid19.ca.gov/safer-economy](https://covid19.ca.gov/safer-economy)

Source: <https://www.ocregister.com/2021/02/07/coronavirus-1187-new-cases-46-new-deaths-in-orange-county-as-of-feb-7>

## Daily cases



Orange County hospitalizations and ICU patients:



## Orange County's tier rating

Positive cases per 100K                      39  
 Testing positivity rate:                      10.9%  
 State threshold:                                  >8%

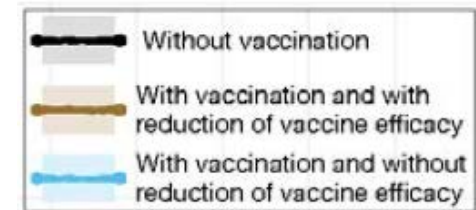
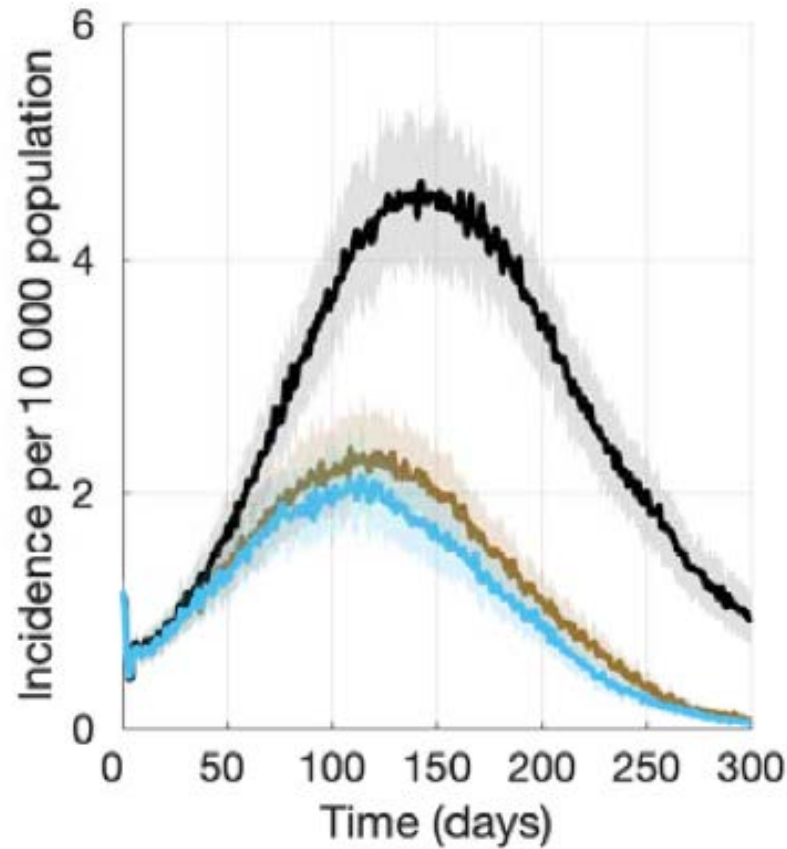
	Rate /100K	Test positivity
<span style="display:inline-block; width:15px; height:15px; background-color:purple;"></span> Widespread	>7	>8%
<span style="display:inline-block; width:15px; height:15px; background-color:darkred;"></span> Substantial	4-7	5-8%
<span style="display:inline-block; width:15px; height:15px; background-color:orange;"></span> Moderate	1-3.9	2-4.9%
<span style="display:inline-block; width:15px; height:15px; background-color:yellow;"></span> Minimal	<1	<2%

California assigns each county to a tier, based on the prevalence of the coronavirus in the community, that determines how tightly businesses will be restricted. Details at: [covid19.ca.gov/safer-economy](https://covid19.ca.gov/safer-economy)

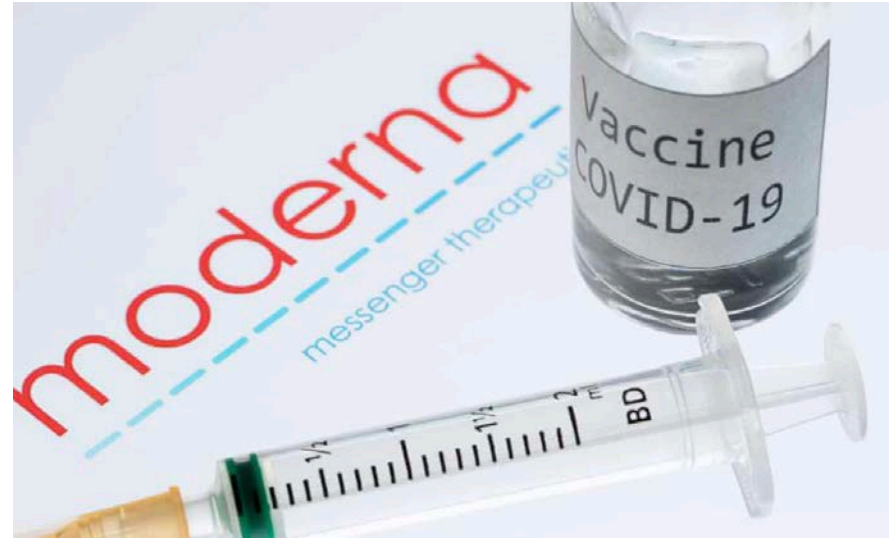
As of 2/7/2021

Source: <https://www.oeregister.com/2021/02/07/coronavirus-1187-new-cases-46-new-deaths-in-orange-county-as-of-feb-7>

## Projected daily incidence of COVID-19 per 10,000 population



- Assuming 95% vaccine efficacy
- Reference point OC 2/7/21 = 3.9/10K



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# COVID-19 Vaccines: Vaccine Basics

*Robert Spitale, Ph.D.  
Founding Associate Dean of Research and Professor  
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School of Pharmacy & Pharmaceutical Sciences*

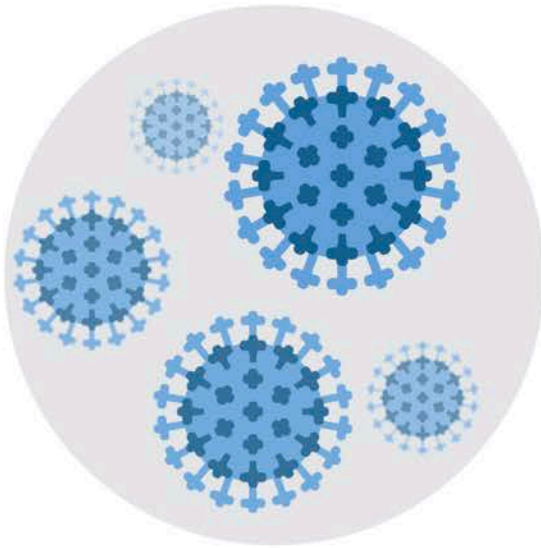
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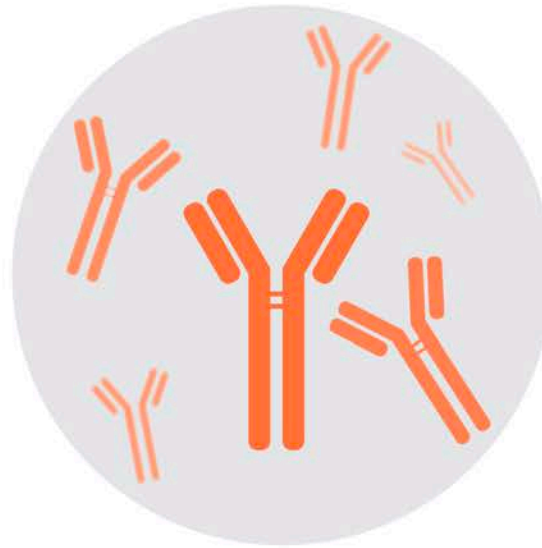
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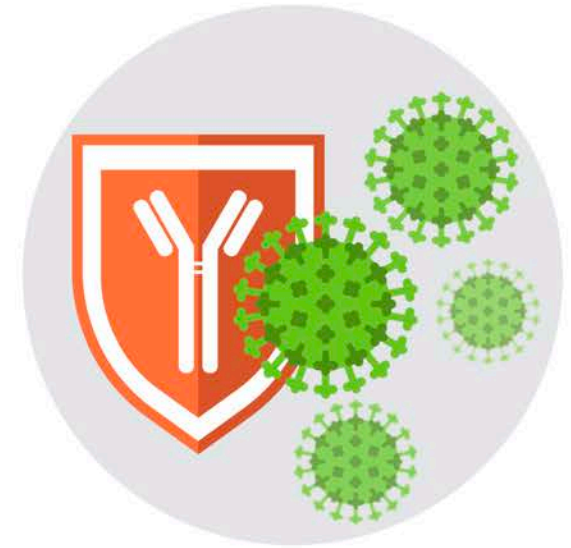
# How do vaccines work?



Vaccines introduce a weak or inactive form of the disease to the body.



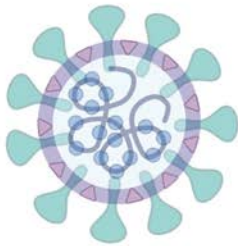
The body reacts by stimulating the immune system and creating antibodies.



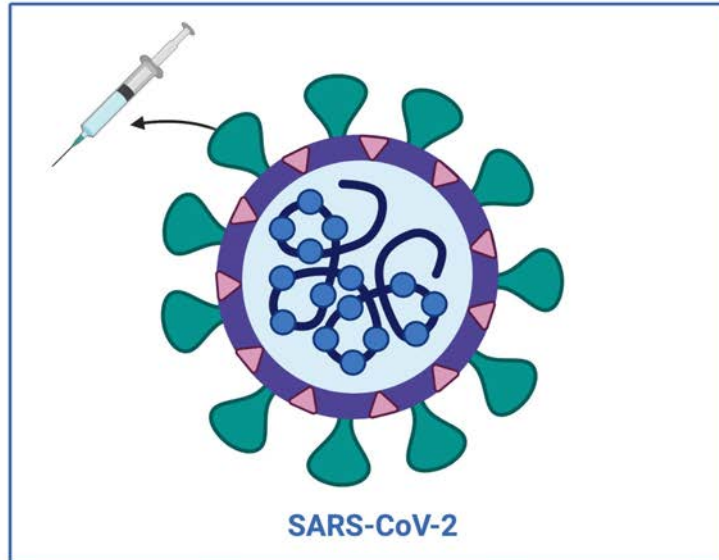
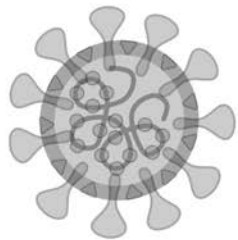
The antibodies remember the disease and can defend against it if a person becomes exposed to it.

## Types of vaccines under development for SARS-CoV2

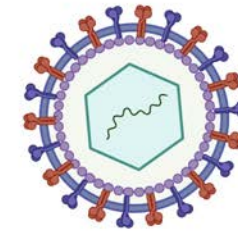
a. Live attenuated



b. Whole inactivated



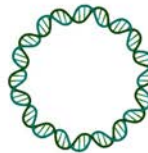
f. Recombinant viral vectors



c. RNA



d. DNA

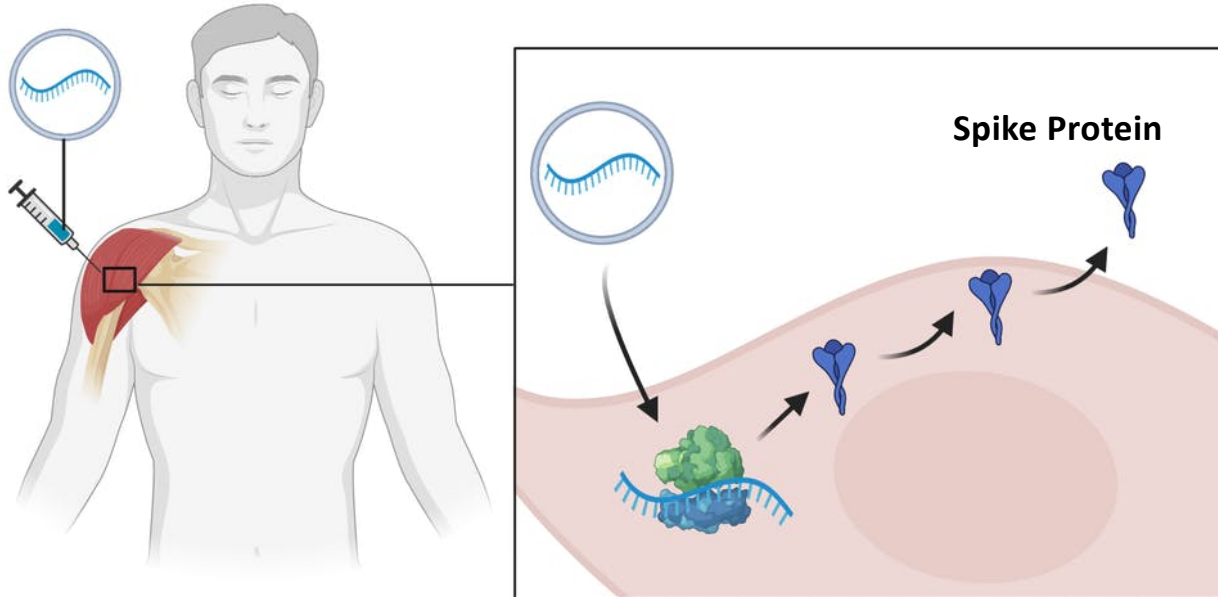


e. Recombinant subunits



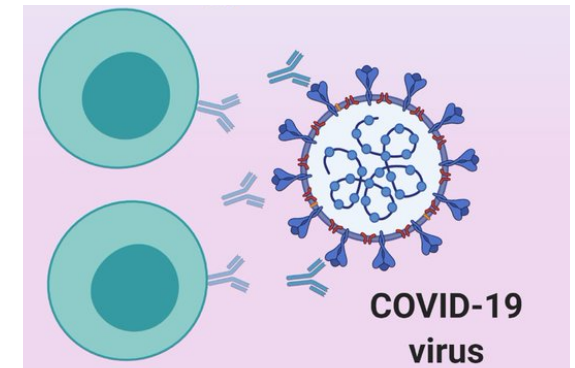
## How does the mRNA vaccine work?

mRNA  
in Capsule



mRNA  
Translation

FUTURE INFECTIONS



Your body will now recognize the spike protein if you are infected. Your immune system will fight off virus now.

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# Current COVID Vaccines: Efficacy and Safety

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Founding Chair and Professor of Clinical Pharmacy  
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# Who participated in the COVID vaccine trials?

## Pfizer-BioNTech

- **16+ years old**
- **43,448** analyzed
- **150** clinical sites
  - 39 U.S. states
- Racial/ethnic distribution
  - **28%** - Hispanic or Latinx
  - **9%** - African American
  - **4%** - Asian
  - **1%** - Native American
- **42%** ages 56-85



## Moderna

- **18+ years old**
- **30,351** analyzed
- **89** clinical sites
  - 32 U.S. states
- Racial/ethnic distribution
  - **20%** - Hispanic or Latinx
  - **10%** - Black or African American
  - **4%** - Asian
  - **3%** - All others
- **25%** ages 65+



# How effective are currently available vaccines?

- Pfizer-BioNTech Vaccine (n=43,931)
  - **Efficacy to prevent an infection: 95%**
    - All COVID-19 cases: placebo=162 cases vs. vaccine=8 cases
    - Severe COVID-19 cases: placebo=9 cases vs. vaccine=1 case
- Moderna Vaccine (n=30,420)
  - **Efficacy to prevent an infection: 94%**
    - All COVID-19 cases: placebo=185 cases vs. vaccine=11 cases
    - Severe COVID-19 cases: placebo=11 cases vs. vaccine=0 case
- Transmission risk and precautions remain

Polark FP, et al. *N Engl J Med* 2020; 383:2603-2615

Barden LR, et al. *N Engl J Med* 2020; 384:403-416

# Safety concerns: What's in the vaccines?

- mRNA
- Lipids – polyethylene glycol (PEG2000)
- Salts
- Sucrose
- Buffers
- Diluent



*None of the vaccines contain eggs, gelatin, latex, preservatives, or adjuvants*



# Safety of COVID-19 mRNA vaccines (I)

- No significant safety concerns identified in the clinical trials
- Very likely to produce side effects after vaccination
  - Non-infectious “flu-like” symptoms
    - Mounting an immune response
  - Pain at injection site
- After vaccination, you can use over-the-counter medications such as acetaminophen (e.g., Tylenol®) and ibuprofen (e.g., Motrin®, Advil®) to manage symptoms

**SAFETY FIRST!**



# Safety of COVID-19 mRNA vaccines (II)

Between December 10-23, 2020

1.9 million first doses  
of Pfizer-BioNTech  
COVID-19 vaccine



21 cases of anaphylaxis

- Average onset = 13 minutes
- 17/21 had a history of allergic reactions

Between December 21, 2020 – January 10, 2021

4 million first doses  
of Moderna  
COVID-19 vaccine

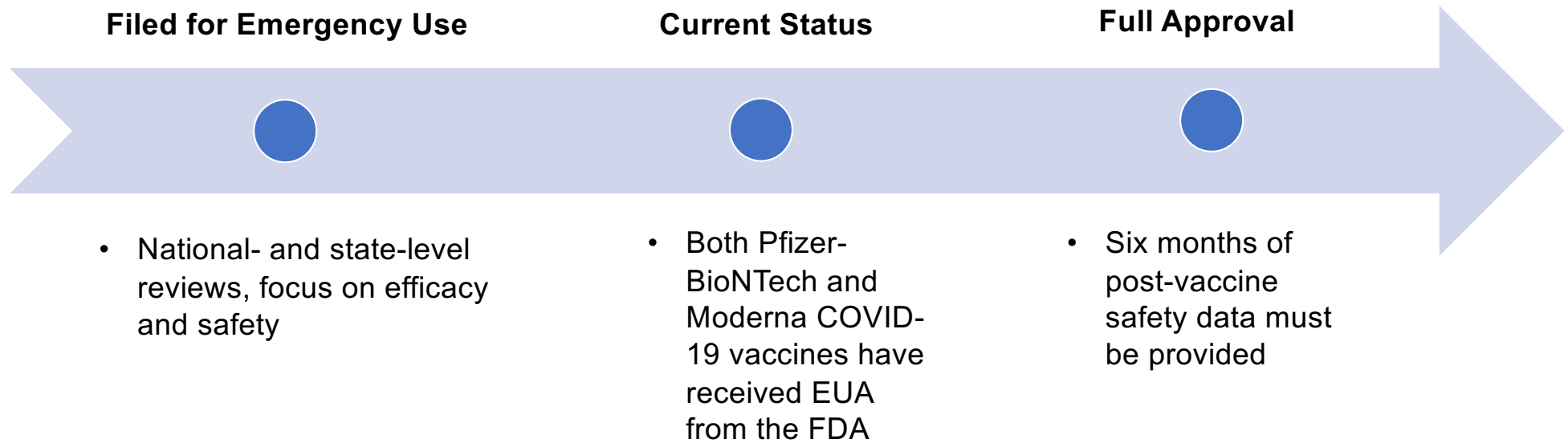


10 cases of anaphylaxis

- Average onset = 7.5 minutes
- 9/10 had a history of allergic reactions

- Close observation after vaccine administration (15-30 mins)
- Very severe reactions are extremely rare, and they are also very treatable

# The Journey of Approval



# Safety Monitoring

**VAERS** Vaccine Adverse Event Reporting System  
[www.vaers.hhs.gov](http://www.vaers.hhs.gov)



# COVID-19 Vaccine Logistics: Administration, Distribution & Allocation

Keri Hurley-Kim, PharmD, MPH, BCACP, APh

*Health Sciences Assistant Clinical Professor*

*Department of Clinical Pharmacy Practice, School of Pharmacy & Pharmaceutical Sciences*

*Vice Chair, Immunization Coalition of LA County*

# COVID-19 Vaccines Administration

## Pfizer-BioNTech

- Two intramuscular doses
  - Injected into deltoid muscle
- Separated by at least 21 days



## Moderna

- Two intramuscular doses
  - Injected into deltoid muscle
- Separated by at least 28 days



# COVID-19 Vaccines

## Storage & distribution

### Pfizer-BioNTech

- Must be stored at ultra-cold temperatures
  - $-70^{\circ}\text{C}$  ( $-94^{\circ}\text{F}$ )
  - Dry ice or specialized freezers
- **Many** logistical challenges

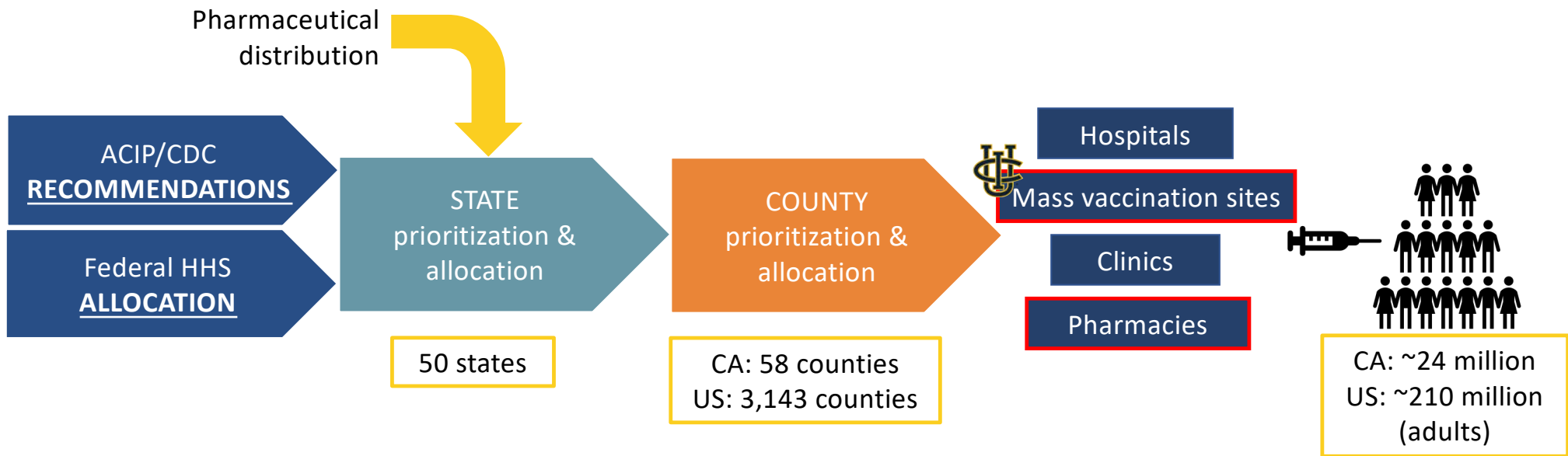
### Moderna

- Can be stored at household freezer temperatures
  - **About  $-20^{\circ}\text{C}$  ( $0^{\circ}\text{F}$ )**
- **Some** logistical challenges



# COVID-19 Vaccines

## Distribution process



# COVID-19 Vaccines

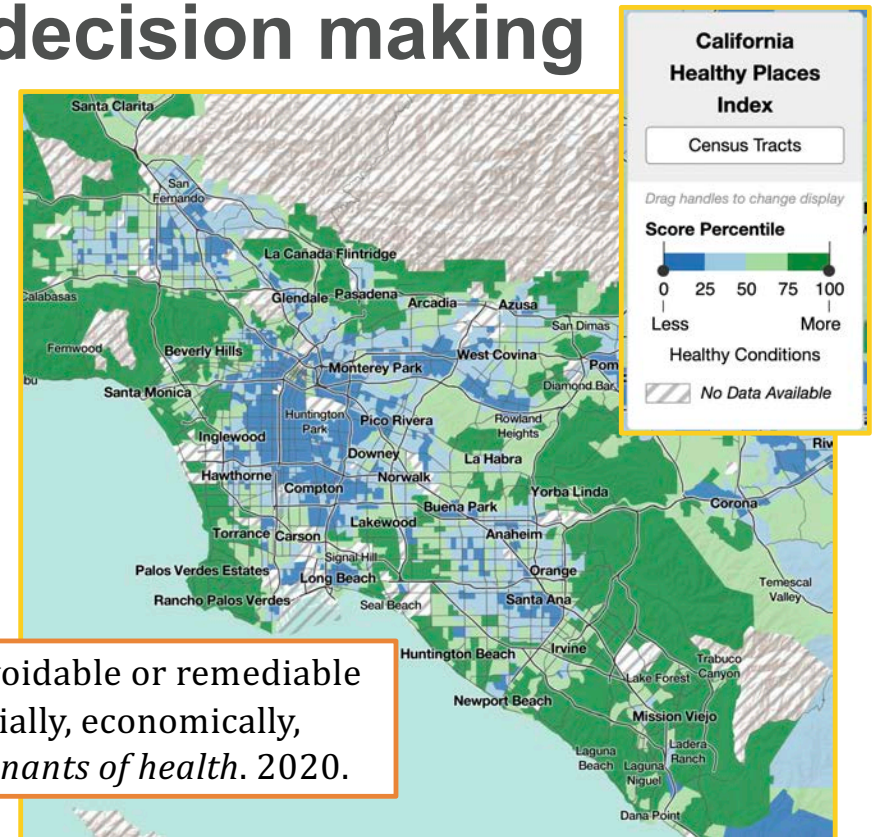
## Allocation and prioritization decision making

### Factors

1. Maximizing benefit, minimizing harm\*
2. **Equity\***
3. Efficiency, minimizing disuse

\*Evidence-based

**Health equity** "...is defined as the absence of unfair and avoidable or remediable differences in health among population groups defined socially, economically, demographically or geographically". - WHO. *Social determinants of health*. 2020.





# COVID-19 Vaccines

## Tiered roll-out

PHASE	CDC/ACIP recommendations as of Dec 20, 2020	Additional federal guidance on Jan. 12, 2021	California updated Jan. 13, 2021	Orange County updated Jan. 11, 2021	LA County updated Jan. 21, 2021
1A	Health care workers & long-term care	-	Health care workers & long-term care	Health care workers & long-term care & age 65+	Health care workers + long-term care
1B	Age 75+ & frontline essential workers	Age 65+	Age 65+ & tier 1 frontline essential workers & tier 2 essential workers then incarcerated, unhoused	Tier 1 frontline essential workers <u>then</u> incarcerated, unhoused, tier 2 essential workers	Age 65+ <u>then</u> tier 1 frontline essential workers & incarcerated, unhoused
1C	Age 65-74 & high risk conditions & other essential workers	-	Age 50-64 & high risk conditions & other essential workers	Age 50-64 & high risk conditions & other essential workers	Age 50-64 & high risk conditions & other essential workers
2	Healthy younger adults		Healthy younger adults	Healthy younger adults	Healthy younger adults

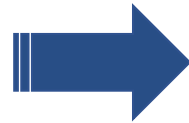
# COVID-19 Vaccines

## Tiered roll-out

### California's at-risk essential worker vaccination plan

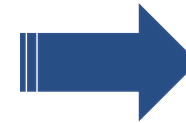
#### Frontline essential workers (tier 1)

- **Education** and childcare
- Emergency services
- Food and agriculture



#### Frontline essential workers (tier 2)

- Transportation and logistics
- Industrial, commercial, residential, sheltering facilities
- Critical manufacturing

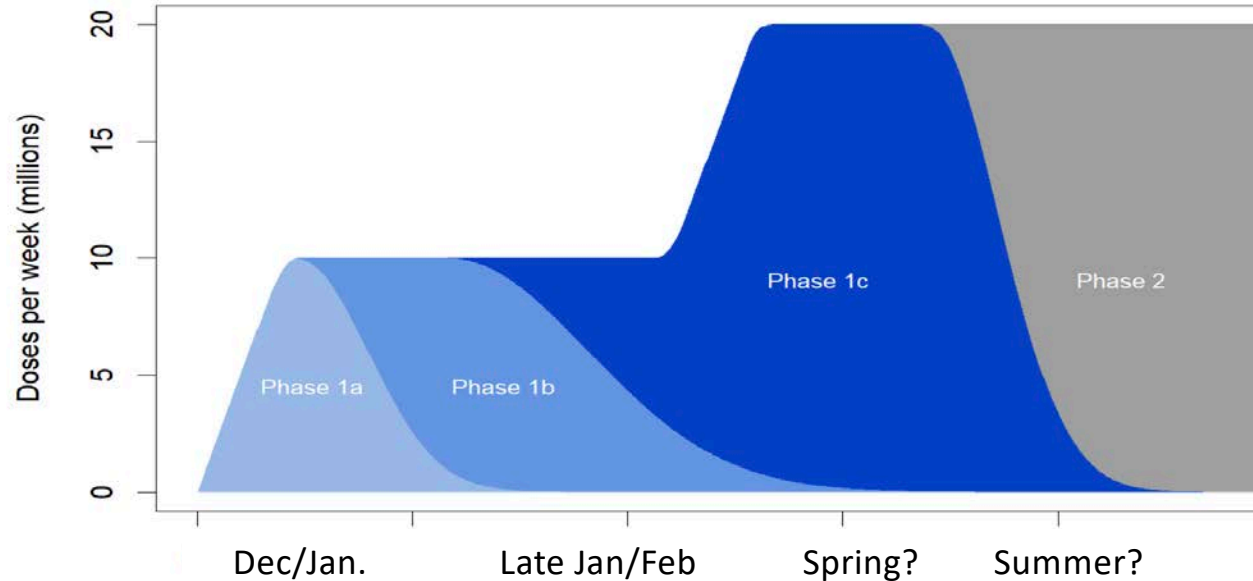


#### Other essential workers (phase 1C)

- Water/wastewater
- Defense
- Energy
- Communications and IT
- Financial services
- Government operations and essential community functions

# COVID-19 Vaccines

## Estimated timing



### Factors in timing for groups/individuals

- Doses available
- Prioritization
- Uptake
- Efficiency and process
  - Impacts of COVID surge
- Location

*Adapted from CDC ACIP meeting materials 12/20/20*

# COVID-19 Vaccines

## Where to find more information

### Centers for Disease Control and Prevention (CDC)

- COVID-19 Vaccine website
  - FAQs and “8 Things to Know”

### State and county public health

- Information about eligible groups
- How to schedule appointments

**Orange County:** [Othena.com](https://www.othena.com)

**Los Angeles County:**

1. [VaccinateLACounty.com](https://www.vaccinatelacounty.com) or
2. [Carbonhealth.com/covid-19-vaccines](https://www.carbonhealth.com/covid-19-vaccines)

# Additional Resources

## **UCI Forward**

<https://uci.edu/coronavirus/>

## **Orange County Health Care Agency**

<https://occovid19.ochealthinfo.com>

## **County of Los Angeles Public Health**

<http://publichealth.lacounty.gov/media/Coronavirus/>

## **California for ALL**

<https://covid19.ca.gov>

# Questions?